

### REMARKS

Claims 22, 24, 28 and 38 are rejected as obvious over Levin (5,724,580) in view of Otvos (6,576,471) and Bomback (5,589,104). We first consider these references as applied to pending claim 38.

38. (New) A cardiovascular healthcare management system comprising:
- (a) an infomediary site having databases for cardiovascular healthcare management which includes a database of test results of concentration of subclasses of LDL particles and subclasses of HDL particles from cardiovascular patients;
  - (b) a data entry interface for receiving patient personal data and test results for concentration of subclasses of LDL particles and subclasses of HDL particles storing the data and results in the infomediary site databases;
  - (c) a diagnostic engine for analyzing patient test results for subclasses of LDL particles, subclasses of HDL particles data and identifying patients who do not have hyperlipidemia based on total LDL cholesterol and total HDL cholesterol, but are in need of treatment; and
  - (d) wherein the subclasses of LDL particles and subclasses of HDL particles are levels determined by gradient gel eletrophoresis.

It is conceded in the Office action that:

- (a) Levin fails to expressly disclose test results concentration of subclasses of LDL and subclasses of HDL.

(b) Levin and Otvos fail to disclose subclasses of LDL and subclasses of HDL determined by gradient gel electrophoresis.

At the time the invention was made, it was not known that levels of subclasses of LDL and subclasses of HDL could identify apparently normal patients,( i.e., normal total HDL and total LDL values) who were in need of treatment.

This relationship could only be determined through a large database, such as that described in the pending application. We see no suggestion in the prior to combine the references to obtain the claimed invention.

The declaration of David T. Shewmake points out that (a) the Berkely HeartLab data is not publicly available (§ 4) and (b) the method of Otvos is not capable of determining the in excess of 40% of subjects with normal HDL and LDL levels who are in need of treatment (§ 5).

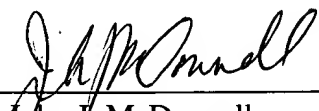
Bombeck (U.S. Patent 5,589,104) likewise does not disclose or suggest identifying patients with normal HDL and LDL values who are in need of treatment base and subclass of HDL and subclass of LDL values.

Clearly, applicants invention was not known, i.e., does not lack novelty.

Applicants invention provides a highly unexpected and valuable clinical result: that patients with normal total LDL and HDL values can be identified as patients at risk by examining their LDL subclasses and HDL subclasses. This unexpected result could only be learned by examining applicants database. Furthermore, the Declaration of David Shewmake describes why the Otvos reference is not capable of achieving the claimed invention.

Allowance of claims 38 and 22-28 and passage of the case to issue are solicited.

Respectfully submitted,

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